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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,875	03/08/2004	Keith G. Lurie	016354-005213US	2670
20350 7590 02/03/2010 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER PATEL, NIHIR B	
			ART UNIT 3772	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/796,875	Applicant(s) LURIE ET AL.	
	Examiner NIHIR PATEL	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Amendment filed on 08/25/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/04/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on August 25th, 2009 have been fully considered and are persuasive. In reference to claims 1, 17 and 24, the applicant argues that by adding the limitation "...wherein the vacuum is maintained for at least 0.5 second..." overcomes the current prior art. The examiner agrees with applicant's argument. However after reviewing the applicant's specification, no where does it recite "...wherein the vacuum is maintained for at least 0.5 second..."

Response to Amendment

2. The examiner acknowledges the amendment filed on August 25th, 2009. The amendment comprises amending claims 1, 17 and 24; and adding new claim 25.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims **1-24** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim(s) contains subject matter specifically "...wherein the vacuum is

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maintained for at least 0.5 second...” which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed has possession of the claimed invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims **1-23 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Weisfeldt et al. (US 4,397,306).

8. **As to claims 1, 4, 10, 14-23 and 25**, Weisfeldt substantially discloses method steps of delivering a positive pressure breath to the person (**see col. 5 lines 15-25**); extracting respiratory gases from the person's airway using a vacuum following the positive pressure breath to create an intrathoracic vacuum to lower pressures in the thorax to maintain a negative pressure (**see col. 5 lines 20-30**) and to enhance blood flow back to the heart (**see col. 2 lines 20-30**); and

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repeating the steps of delivering positive pressure breaths and extracting respiratory gases to thereby treat said person suffering from said ailment (**see col. 2 lines 55-68 and col. 3 lines 1-4**), but does not disclose maintaining a negative pressure between 0 mmHg to about -50 mmHg or the vacuum that is maintained for at least 0.5 second. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by providing a negative pressure between 0 mmHg to about -50 mmHg in order to extract the proper amount of respiratory gases within the patient, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by providing a method step wherein the vacuum is maintained for at least 0.5 second in order remove any carbon dioxide left in the patient's system, Since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

9. **As to claim 2**, Weisfeldt substantially discloses method steps wherein the person is suffering from an ailment from a group consisting of head trauma, elevated intracranial pressures, low blood pressure; low blood circulation, low blood volume, cardiac arrest, hypotension, shock, hypertension, intraocular pressures and heart failure (**see col. 3 lines 20-30**).

10. **As to claim 3**, Weisfeldt substantially discloses method steps regulating the amount of intrathoracic vacuum using a threshold valve that is in fluid communication with the person's airway (**see col. 4 lines 28-39**).

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11. **As to claim 5**, Weisfeldt substantially discloses method steps of stopping application of the vacuum when applying the positive pressure breath using a switching arrangement (**see col. 4 lines 51-55**).

12. **As to claim 6**, Weisfeldt substantially discloses method steps wherein the positive breath is delivered using source selected from a group consisting of a mechanical ventilator, a hand held bag valve resuscitator, mouth-to-mouth, or a means to provide intermittent positive pressure (**see col. 4 lines 10-23**).

13. **As to claim 7**, Weisfeldt substantially discloses method steps wherein the respiratory gases are extracted with a constant extraction, varied over time or pulsed extraction (**see col. 5 lines 20-30**).

14. **As to claim 11**, Weisfeldt substantially discloses method steps wherein the vacuum is maintained with negative flow or without flow (**see col. 5 lines 20-30**).

15. **As to claim 13**, Weisfeldt substantially discloses method steps wherein the respiratory gases are extracted using equipment selected from a group consisting of a mechanical ventilator, a vacuum with vacuum regulator, a phrenic nerve stimulator, an extrathoracic vest, a ventilator bag, and an iron lung cuirass device (**see col. 4 lines 10-23**).

16. **As to claim 8**, Weisfeldt substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose breath being delivered for a time in the range for about 250 milliseconds to about 2 second. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by providing a breath being delivered for a time in the range for about 250 milliseconds to about 2 second in order to provide the patient with the correct amount of ventilation, since it has been held that where the general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. ***In re Aller*, 105 USPQ 233.**

17. **As to claim 9**, Weisfeldt substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a breath that is delivered at a rate in the range from about 0.1 liters per seconds to about 5 liters per second. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by providing a breath that is delivered at a rate in the range from about 0.1 liters per seconds to about 5 liters per second in order to provide the patient with the correct amount of ventilation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. ***In re Aller*, 105 USPQ 233.**

18. **As to claim 12**, Weisfeldt substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose the time the positive pressure breath is supplied relative to the time in which respiratory gases are extracted is in the range from about 0.5 to about 0.1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by providing the time the positive pressure breath is supplied relative to the time in which respiratory gases are extracted is in the range from about 0.5 to about 0.1 in order to provide the patient with the correct amount of ventilation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. ***In re Aller*, 105 USPQ 233.**

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19. **As to claim 17**, Weisfeldt substantially discloses an apparatus that comprises a means to interface with the patient's airway **12 (see figs. 4 and 5; col. 4 lines 10-20)**; a means to repeatedly extract respiratory gases from the patient's lungs and airway to create and periodically maintain a negative intrathoracic pressure (**see col. 4 lines 15-25; col. 5 lines 15-30**); a means to repeatedly regulate the extraction of respiratory gases within the patient's lungs and airway (**see col. 4 lines 15-25; col. 5 lines 15-30**); and a means to deliver a positive pressure breath, to periodically provide inspiration of respiratory gases (**see col. 4 lines 10-40 and col. 5 lines 15-40**) but does not disclose gases that are extracted for at least 0.5 second. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by extracting gases for at least 0.5 second in order remove any carbon dioxide left in the patient's system, Since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

20. **As to claim 18**, Weisfeldt substantially discloses an apparatus wherein the means to extract respiratory gases comprises vacuum source selected from a group consisting of a suction line or venturi device to an oxygen tank (**see col. 4 lines 10-23**).

21. **As to claim 19**, Weisfeldt substantially discloses an apparatus that further comprises a switching mechanism to stop the extraction of respiratory gases during delivery of a positive pressure breath, wherein the switching mechanism is selected from a group consisting of mechanical devices, magnetic devices, and electronic devices (**see col. 4 lines 51-55**).

22. **As to claim 20**, Weisfeldt substantially discloses an apparatus wherein the means for extracting respiratory gases is selected from a group consisting of a mechanical ventilator, a

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vacuum with vacuum regulator, a phrenic nerve stimulator, an extrathoracic vest, a ventilator bag, and an iron lung cuirass device (**see col. 4 lines 10-23**).

23. **As to claim 21**, Weisfeldt teaches an apparatus wherein the means for regulating comprises a threshold valve that is in fluid communication with the person's airway (**see col. 4 lines 28-39**).

24. **As to claim 23**, Weisfeldt teaches an apparatus wherein the means for delivering a positive pressure breath is selected from a group consisting of a mechanical ventilator, a hand held bag valve resuscitator, mouth-to-mouth, or a means to provide intermittent positive pressure ventilation (**see col. 4 lines 10-23**).

25. Claim **24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Weisfeldt et al. (US 4,397,306) in view of Abramov et al. (US 5,806,512)

26. **As to claim 24**, Weisfeldt substantially discloses a vacuum source in fluid communication with the housing for repeatedly extracting respiratory gases from the person's lungs and airway to create and periodically maintain a negative intrathoracic pressure (**see col. 4 lines 20-30 and col. 5 lines 20-30**); a vacuum regulator to regulate the extraction of respiratory gases from the patient's lungs and airway (**see col. 4 lines 28-39**); and a positive pressure source in fluid communication with the housing for intermittently supplying positive pressure breaths to the person (**see col. 4 lines 10-30 and col. 5 lines 15-30**) but does not disclose a housing having an interface that is adapted to couple the housing to the person's airway. Abramov teaches an apparatus that does disclose a housing **38 (see fig. 1)** having an interface that is adapted to couple the housing to the person's airway. Therefore, it would have been obvious to one having ordinary

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skill in the art at the time the invention was made to modify Weisfeldt's invention by providing a housing having an interface that is adapted to couple the housing to the person's airway as taught by Abramov in order prevent leakage.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772